

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

Display Date 8.17.04  
Publication Date 8.18.04  
Certifier A. Corbin

DDM

**New Animal Drugs for Use in Animal Feeds; Carbadox and Oxytetracycline**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Phibro Animal Health. The NADA provides for the use of approved, single-ingredient Type A medicated articles containing carbadox and oxytetracycline to formulate two-way combination drug Type C medicated feeds for swine.

**DATES:** This rule is effective *[insert date of publication in the Federal Register]*.

**FOR FURTHER INFORMATION CONTACT:** Joan C. Gotthardt, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7571, e-mail: [joan.gotthardt@fda.gov](mailto:joan.gotthardt@fda.gov).

**SUPPLEMENTARY INFORMATION:** Phibro Animal Health, 710 Rt. 46 East, suite 401, Fairfield, NJ 07004, filed NADA 141-211 that provides for the use of MECADOX (carbadox), approved under NADA 41-061, and TERRAMYCIN (oxytetracycline) Type A medicated articles, approved under NADA 95-143, to formulate two-way combination drug Type C medicated feeds for swine. The Type C medicated feeds are used for treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* susceptible to oxytetracycline, for treatment of bacterial pneumonia caused by *Pasteurella multocida*

susceptible to oxytetracycline; and for increased rate of weight gain and improved feed efficiency. The application is approved as of July 21, 2004, and the regulations are amended in 21 CFR 558.115 and 558.450 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

#### **List of Subjects in 21 CFR Part 558**

Animal drugs, Animal feeds.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

#### **PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS**

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

- 2. Section 558.115 is amended by adding paragraph (d)(4) to read as follows:

**§ 558.115 Carbadox.**

\* \* \* \*

(d) \* \* \*

(4) *Amount.* Carbadox, 10 to 25 grams per ton of feed; plus oxytetracycline, 10 milligrams per pound of body weight.

(i) *Indications for use.* For treatment of bacterial enteritis caused by *Escherichia coli* and *S. choleraesuis* susceptible to oxytetracycline, for treatment of bacterial pneumonia caused by *Pasteurella multocida* susceptible to oxytetracycline; and for increased rate of weight gain and improved feed efficiency.

(ii) *Limitations.* Feed continuously for 7 to 14 days. Not for use in pregnant swine or swine intended for breeding purposes. Do not feed to swine within 42 days of slaughter.

- 3. Section 558.450 is amended by redesignating paragraph (d)(3)(i) as paragraph (d)(3)(iv); and by adding new paragraph (d)(3)(i) to read as follows:

**§ 558.450 Oxytetracycline.**

\* \* \* \*

(d) \* \* \*

(3) \* \* \*

(i) Carbadox as in § 558.115 of this chapter.

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Dated: 8-2-04  
August 2, 2004.

*Linda Tollefson*

Linda Tollefson,  
Acting Director,  
Center for Veterinary Medicine.

[FR Doc. 04-???? Filed ??-??-04; 8:45 am]

BILLING CODE 4160-01-S

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